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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,360	12/20/2001	Robert John Kodrzycki	FSL 96-1 CIP	4331

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/029,360	<b>Applicant(s)</b> KODRZYCKI ET AL.	
	<b>Examiner</b> Cynthia Collins	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The Amendment filed June 7, 2004, has been entered.

Claims 1, 4-7 and 10-12 are currently amended.

Claims 1-21 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claims 1-21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed December 8, 2003.

Applicant's arguments filed June 7, 2004 have been fully considered but they are not persuasive.

Applicant traverses the rejection in view of the amendments to claims to remove the phrase "gene of interest" and to specify that the bombarding gene is capable of transforming *Pinus* or *Pinus* interspecies hybrids. Applicant submits that a person of ordinary skill in the art is well aware of which genes are able to transform *Pinus* or *Pinus* interspecies hybrids, and those which are not. Moreover, Applicant submits that such knowledge could be gained by a skilled artisan with only a minimum amount of experimentation (reply page 9).

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The rejection is maintained because the claimed invention is not adequately described. That "gene of interest" has been replaced with "gene which is capable of transforming *Pinus* or *Pinus* interspecies hybrids" does not further describe the claimed invention. Because all genes have the same chemical structure (polynucleotide), all genes are capable of transforming *Pinus* or *Pinus* interspecies hybrids, as any polynucleotide may be introduced into a cell by transformation techniques. The phrase "gene which is capable of transforming *Pinus* or *Pinus* interspecies hybrids" recites no specific function performed by such a gene once transformed into a plant, nor any specific structural features unique to members of the genus. Because the genus "gene which is capable of transforming *Pinus* or *Pinus* interspecies hybrids" is not adequately described, transgenic *Pinus* conifer plants transformed with a genetic construct comprising at least one gene which is capable of transforming *Pinus* or *Pinus* interspecies hybrids are also not described.

Claims 1-21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed December 8, 2003.

Applicant's arguments filed June 7, 2004 have been fully considered but they are not persuasive.

Applicant traverses the rejection in view of the amendments to claims to remove the phrase "gene of interest" and to specify that the bombarding gene is capable of transforming

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*Pinus* or *Pinus* interspecies hybrids. Applicant submits that a person of ordinary skill in the art is well aware of which genes are able to transform *Pinus* or *Pinus* interspecies hybrids, and those which are not. Moreover, Applicant submits that such knowledge could be gained by a skilled artisan with only a minimum amount of experimentation (reply page 9).

The rejection is maintained because the claimed invention is not enabled. That “gene of interest” has been replaced with “gene which is capable of transforming *Pinus* or *Pinus* interspecies hybrids” in the amended claims does not enable the claimed invention. The specification does not provide sufficient guidance with respect to which genes should be used to transform *Pinus* or *Pinus* interspecies hybrids or how to express such genes in order to produce plants that exhibit a particular useful phenotype. Absent such guidance one skilled in the art would have to identify from among the numerous genes available for transformation those that could be used to impart a particular useful phenotype on *Pinus* or *Pinus* interspecies hybrids transformed therewith, and then test each such gene in variety of different constructs in order to determine how to express such genes in a manner that would impart a particular useful phenotype to a plant transformed therewith. Such a trial and error experimental approach to practicing the claimed invention would constitute undue experimentation. Furthermore, it is not the province of one skilled in the art to compensate for the inadequacy of the disclosure. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997):

While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention ... It is true ... that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement.

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However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

***Claim Rejections - 35 USC § 102***

Claims 1-21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Walter et al. (WO 97/01641, International Publication Date 16 January 1997, Applicant's IDS), for the reasons of record set forth in the office action mailed December 8, 2003.

Applicant's arguments filed June 7, 2004 have been fully considered but they are not persuasive.

Applicant argues that Walter et al. does not anticipate the claimed invention because the Walter et al. reference teaches a method for stably inserting foreign genes into conifer cells wherein the cells to be transformed are in an undifferentiated state such that embryos are likely to regenerate, whereas applicants teach and claim transgenic conifer plants which are produced by a different method, namely from the transformation of differentiated conifer tissues (reply pages 9-10). Applicant further points to *Schroeder v. Owens-corning Fiberglass Corp.*, 514 F2d 901, 185 USPO 723 (1975, CA 9 Cal) as holding that unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in a single prior art reference, there is no anticipation, such that one skilled in the art would recognize that applicant's invention would not be anticipated by the method of Walter et al. (reply pages 10-11).

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That the transgenic *Pinus* conifer plants taught by Walter et al. were manufactured by a method different from applicant's was acknowledged in the rejection set forth at page 7 of the office action mailed December 8, 2003. The rejection is maintained because Walter et al. need not teach applicant's method in order to anticipate the claimed plants. The plants made by the method of Walter et al. appear to be indistinguishable from the plants made by applicant's method. See *In re Thorpe*, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

A handwritten signature in black ink, appearing to read "Amy Nelson". The signature is fluid and cursive, with the first name "Amy" and last name "Nelson" clearly distinguishable.

AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600